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83. (New) The osteoimplant of Claim 82 wherein the elongate bone-derived particles are selected from the group consisting of nondemineralized bone particles, demineralized bone particles and mixtures thereof.

84. (New) The osteoimplant of Claim 77 further comprising a biocompatible component selected from the group consisting of biocompatible fluid carrier, filler, fiber, mesh, substance providing radiopacity, plasticizer, biostatic/biocidal agent, surface active agent and bioactive substance.

#### REMARKS

This amendment responds to the Advisory Action mailed August 16, 2002 and further responds to the final Office Action mailed June 13, 2002. Claims 1-13 and 33-35 have been deleted and new Claims 41-84 have been added. The specification of the application has also been amended to include material from U.S. Application Serial No. 09/211,310, filed December 14, 1998, the contents of which were incorporated by reference into this application (see page 27 of the specification).

Claim 41, one of three independent claims in the newly added claims, is directed to an osteoimplant in the form of a flexible sheet comprising a coherent mass of elongate bone-derived particles possessing a void volume of not greater than about 32%. The second independent claim, Claim 70, is directed to an osteoimplant in the form of a flexible sheet comprising a coherent mass of elongate bone-derived particles, the sheet having a thickness of from about 50 to about 2000 microns. Claim 77, the third

independent claim presented herein, is directed to an osteoimplant comprising a coherent mass of elongate bone-derived particles and a binder, said mass possessing a void volume of not greater than about 32%.

In the final Office Action dated June 13, 2002, the Examiner cited Chen et al. U.S. Patent No. 5,707,962 ("Chen et al.") as anticipating previously pending Claims 1, 3-7, 10-13 and 33-35 under 35 U.S.C. §102(b) and as rendering obvious previously pending Claims 2, 8 and 9 under 35 U.S.C. §103(a).

In their response to the aforesaid Office Action (paper 11 submitted on July 30, 2002), applicants pointed out that Chen et al. contains no express or inherent disclosure of (1) elongate bone particles or (2) a void volume of not greater than about 32%, and thus neither anticipated nor rendered obvious the invention of the previously pending claims. In response, the Examiner issued an Advisory Action asserting that (1) Chen et al. discloses elongate particles because its particles "will not be perfect spheres even after processing" and that (2) Chen et al. discloses "a semi-porous structure which can be construed to have a lowered [sic] void volume than one that is porous, such that 'semi' can be 'about' 32%".

As with the previously pending claims, new Claims 41-84 are similarly directed to osteoimplants comprising *elongate bone-derived particles*, and in the case of most of the new claims (specifically, Claims 41-69 and 77-84), with the osteoimplants possessing a *void volume not greater than about 32%*. It is respectfully submitted that the Examiner is

manifestly in error in asserting that the Chen et al. osteogenic composition contains elongate bone-derived particles and possesses a void volume not greater than about 32%.

The Examiner's comment in the Advisory Action that Chen et al.'s particles may be elongate because they are not all "perfect spheres" implies that anything other than a perfect sphere is an elongated particle. In this view of the matter, such common substances as ordinary table salt, granulated sugar, ground pepper, ground coffee, flour, etc., none of which are made up of "perfect spheres", could be considered "elongated particles". It is highly doubtful that anyone familiar with these and similar particulate materials would consider any of them to be elongated particles. The Examiner's view to the contrary is manifestly an unreasonable one. Indeed, the Examiner's understanding of what is embraced by the term "elongate" is wholly contrary to the dictionary definition of the term (see the entry for "elongate" in Webster's Third New International Dictionary, 1986, p. 737, a copy of which is attached hereto, which defines this term as "having a form notably long in comparison to its width"). Against an unreasonable construction of a claim term, the Board of Patent Appeals and Interferences in *Ex parte Crissy et al.*, 201 U.S.P.Q. 689, 693 (Bd. Pat. App. and Int., 1976) has relied on a dictionary definition to ascertain the correct and intended meaning of a term. At issue in that case was the proper interpretation of "reciprocative". The Examiner had considered the oscillation of a member about a fixed axis not to be within the definition; the Board of Patent Appeals and Interferences disagreed, noting that the dictionary definition of reciprocate was "to move forward and backward alternatively" which encompassed oscillation. Courts, too, regularly rely on dictionary definitions to construe the ordinary meaning of terms recited

in patent claims. *See e.g., Cybor Corp. v. FAS Technologies, Inc.*, 138 F.3d 1448, 1459, 46 U.S.P.Q.2d 1169, 1177 (Fed. Cir. 1998); *Sage Products, Inc. v. Devon Indus., Inc.*, 126 F.3d 1420, 1430-1431, 44 U.S.P.Q.2d 1103, 1113 (Fed. Cir. 1997); *American Permahedge, Inc. v. Barcana, Inc.*, 105 F.3d 1441, 1444, 41 U.S.P.Q.2d 1614, 1616 (Fed. Cir. 1997); *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 531, 41 U.S.P.Q.2d 1001, 1006 (Fed. Cir. 1996).

Furthermore, the application goes into considerable detail in describing specific embodiments of elongate bone particles. Thus, for example, as set forth in applicants' specification, "elongate" bone particles possess relatively high median length to median thickness ratios. The specification notes that applicants' elongate bone particles possess a median length of from about 2 to about 200 mm or more and preferably from about 10 to about 100 mm, a median thickness of from about 0.05 to about 2 mm and preferably from about 0.2 to about 1 mm, and a median width of from about 1 mm to about 20 mm and preferably from about 2 to about 5 mm. The elongate bone particles thus can possess a median length to median thickness ratio of at least about 50:1 up to about 500:1 or more, preferably from about 50:1 to about 100:1, and a median length to median width ratio of from about 10:1 to about 200:1 and preferably from about 50:1 to about 100:1. Federal Circuit precedent clearly requires that claims are not to be interpreted in a vacuum, but are read, interpreted and understood in view of the specification of which they are a part. *See C.R. Bard Inc. v. M3 Systems Inc.*, 157 F.3d 1340, 1350, 48 U.S.P.Q. 1225, 1230 (Fed Cir. 1998) (citing *Slimfold Mfg. Co. v. Kinkead Indus. Inc.*, 810 F.2d 1113, 1116, 1 U.S.P.Q. 2d 1563, 1566 (Federal Cir. 1987)).

It is the elongate nature of applicants' bone-derived particles which allows them to form a coherent mass. The coherent mass can be formed by mechanical adherence of the elongate bone-derived particles (as recited in new Claims 55 and 79), specifically by entanglement with each other (as recited in new Claims 56 and 80).

Contrary to the Examiner's position, nothing is said in Chen et al. regarding the shape of the demineralized bone "particles". The Chen et al. examples illustrate a product produced from collagen and demineralized bone particles (Examples 1 and 2), where a thick slurry of the combined materials is blended in a Waring Blender. Thus, even if elongate demineralized bone particles were originally present in the slurry (Chen et al. is completely silent on this point), they would have been broken up or chopped into particles possessing roughly the same dimensions of length, width and thickness, i.e., *non-elongate particles*, before the final product (a sponge) was formed. Clearly, the particles of Chen et al. would not possess a form "notably long in comparison to its width" as authoritatively defined in the attached dictionary entry.<sup>1</sup>

Thus, Chen et al. fails to anticipate or render obvious the subject matter of new Claims 41-84 all of which require elongate bone-derived particles.

With respect to the Examiner's assertion in the Advisory Action that Chen et al.'s disclosure of a semi-porous structure can be construed to have a lower void volume than one that is porous, such that "semi" can be "about" 32%, the Examiner's position ignores

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<sup>1</sup> Not only is Chen et al. silent about the size and shape of its particles, it refers to Jefferies U.S. Patent Nos. 4,394,370 and 4,472,840, each of which disclose in Example 1 bone particles of less than 75 millimicrons.

the fact that there is no disclosure in Chen et al., express or inherent, limiting the void volume to *not greater* than about 32%.

In the claims of the subject application, the recitation of less than about 32% pore volume relates directly to the improved properties of the osteoimplant and is a critical limitation thereof. Thus, in table 5 of the application, an implant prepared in accordance with the prior art (and containing a void volume considerably in excess of applicants' claimed maximum) had a much increased tendency to at least partially return to its original bent configuration than an implant prepared in accordance with the claimed invention. Applicants' implant for the most part exhibited no such tendency, or "memory". The advantage of a flexible membrane which exhibits little if any memory is that it will tend to remain conformed to the shape of the site where it is implanted, a desirable characteristic for many kinds of orthopedic surgical procedures.

For the Examiner's position to have any merit, Chen et al. would have to inherently disclose a void volume *necessarily* not greater than about 32 %. The doctrine of inherency holds that a property is necessarily present, given the nature of the disclosure, and is therefore disclosed even though the reference makes no express mention of the property. "If the prior art reference does not expressly set forth a particular element of the claim, that reference still may anticipate if that element is 'inherent' in its disclosure. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q.2d 1949, 1950-51 (Fed. Cir. 1999) (quoting

*Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). Inherency is not, however, "established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can*, 948 F.2d at 1269, 20 U.S.P.Q.2d at 1749 (quoting *In re Oelrich*, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981)). As is clear from the above authoritative pronouncements of the Federal Circuit and its predecessor court, the Court of Customs and Patent Appeals, there is no such thing as inherency "to some extent". Either the "not greater than about 32 %" void volume limitation of the claims is inherently disclosed in Chen et al. or it is not disclosed at all.

In the final Office Action the Examiner placed the burden on applicants to demonstrate that Chen et al.'s osteogenic composition does not possess a void volume of less than 32%. This attempt to shift the burden to applicants is wholly inappropriate and contrary to Board of Patent Appeals and Interferences precedent, as the Examiner has provided no reasonable support for his determination that a void volume *necessarily* not greater than about 32 % *is present* in the porous or semi-porous matrix which is the primary component of Chen et al.'s osteogenic composition.

In *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (Bd. Pat. App. & Inter. 1990), the applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon. The Examiner, in rejecting the claims, applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold. While the reference did not directly state that the end product balloon was biaxially oriented, it did disclose that the balloon was "formed from a thin

flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material.” *Id.* at 1462 (emphasis in original). Using this disclosure, the Examiner argued that Schjeldahl’s balloon was inherently biaxially oriented and that since the Patent and Trademark Office lacked the necessary laboratory equipment for testing, the burden shifted to the applicant to demonstrate Schjeldahl’s balloon was not biaxially oriented. The Board of Patent Appeals and Interferences rejected this argument as follows: “the initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention rests upon the examiner. In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Id.* at 1463-1464 (emphasis in original) (citations omitted). The Board of Patent Appeals and Interferences concluded the Examiner had not discharged his initial burden and reversed the rejection because the Examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.

The Board of Patent Appeals and Interferences reached a similar conclusion in *Ex parte Skinner*, 2 U.S.P.Q.2d 1788 (Bd. Pat. App. & Inter. 1986). In *Skinner*, the applicant’s invention was directed to a mold used to produce plastic articles. The Examiner rejected the claims over a reference to Mizutani, which was directed to a mold used for manufacturing contact lenses, asserting that Mizutani “*may* inherently have the characteristics of the claimed mold.” *Id.* at 1789 (emphasis in original). While recognizing that authority existed for an examiner to require an applicant to prove subject

matter in the prior art lacked a purportedly inherent critical functional limitation, the Board of Patent Appeals and Interferences held there was insufficient reason to place such a burden on the applicant, noting that “before an applicant can be put to this burdensome task, the examiner must provide some evidence or scientific reasoning to establish the reasonableness of the examiner’s belief that the functional limitation is an inherent characteristic of the prior art.” *Id.*

In asserting that Chen et al.’s disclosure of a semi-porous structure can be construed to have a lowered void volume than one that is porous, such that “semi” can be “about” 32%, the Examiner has done no more than present a conclusory allegation regarding a mere possibility. The proper focus is not what “can be” disclosed by Chen et al. but what is, in fact, reasonably disclosed. Nowhere does Chen et al. disclose a void volume necessarily less than about 32%; to the contrary, Chen et al. refer to its product as a “sponge” which is believed to indicate a highly porous material. This is in direct contrast to applicants’ osteoimplant which, as Comparative Example 1 demonstrates, has a void volume not greater than about 32 %. If the Examiner persists in his view that a void volume not greater than 32% is inherent in the Chen et al. description, the Examiner is respectfully requested to specifically identify some evidence or scientific reasoning which supports the Examiner’s assertion that a void volume not greater than about 32 % is *necessarily* present in Chen et al.’s sponge.

For the reasons noted above, Chen et al. neither anticipates nor renders obvious the limitation in independent Claims 41 and 77 that the osteoimplant possess a void volume of not greater than about 32%.

Finally, with respect to the limitation in independent Claim 70 that the osteoimplant comprise a flexible sheet having a thickness of from about 50 to about 2000 microns, Chen et al.'s sponge in no way anticipates or renders obvious applicants' flexible sheets and their thicknesses.

Accordingly, applicants submit that Chen et al. neither anticipates nor renders obvious newly submitted Claims 41-84. Favorable action on the merits of Claims 41-84 presented herein is requested.

Respectfully submitted,



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